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in sufficient detail as to be readily understood and audited;

- (3) Be maintained for not less than 5 years beyond their creation; and
- (4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.
- (c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent.

§ 205.104 [Reserved]

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

- (a) Synthetic substances and ingredients, except as provided in §205.601 or §205.603;
- (b) Nonsynthetic substances prohibited in §205.602 or §205.604;
- (c) Nonagricultural substances used in or on processed products, except as otherwise provided in §205.605:
- (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in § 205.606:
- (e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with § 205.600(a):
- (f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and
 - (g) Sewage sludge.

§§ 205.106-205.199 [Reserved]

Subpart C—Organic Production and Handling Requirements

§205.200 General.

The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must comply with the applicable provisions

of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

§ 205.201 Organic production and handling system plan.

- (a) The producer or handler of a production or handling operation, except as exempt or excluded under §205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:
- (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- (2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable;
- (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- (4) A description of the recordkeeping system implemented to comply with the requirements established in § 205.103:
- (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and
- (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.
- (b) A producer may substitute a plan prepared to meet the requirements of

§ 205.202

another Federal, State, or local government regulatory program for the organic system plan: *Provided*, That, the submitted plan meets all the requirements of this subpart.

§ 205.202 Land requirements.

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as "organic," must:

- (a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;
- (b) Have had no prohibited substances, as listed in §205.105, applied to it for a period of 3 years immediately preceding harvest of the crop; and
- (c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

§ 205.203 Soil fertility and crop nutrient management practice standard.

- (a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.
- (b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.
- (c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:
- (1) Raw animal manure, which must be composted unless it is:
- (i) Applied to land used for a crop not intended for human consumption:
- (ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or
- (iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not

have direct contact with the soil surface or soil particles;

- (2) Composted plant and animal materials produced though a process that:
- (i) Established an initial C:N ratio of between 25:1 and 40:1; and
- (ii) Maintained a temperature of between 131 $^{\circ}F$ and 170 $^{\circ}F$ for 3 days using an in-vessel or static aerated pile system; or
- (iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times
 - (3) Uncomposted plant materials.
- (d) A producer may manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances by applying:
- (1) A crop nutrient or soil amendment included on the National List of synthetic substances allowed for use in organic crop production;
- (2) A mined substance of low solubility;
- (3) A mined substance of high solubility: *Provided*, That, the substance is used in compliance with the conditions established on the National List of nonsynthetic materials prohibited for crop production;
- (4) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: *Provided*, That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of nonsynthetic substances prohibited for use in organic crop production; and
- (5) A plant or animal material that has been chemically altered by a manufacturing process: *Provided*, That, the material is included on the National List of synthetic substances allowed for use in organic crop production established in § 205.601.
 - (e) The producer must not use:
- (1) Any fertilizer or composted plant and animal material that contains a synthetic substance not included on